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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/770,916	01/26/2001	Dara W. Frank	650053.91487	6613

7590 06/10/2002

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EXAMINER	
DUFFY, PATRICIA ANN	

ART UNIT	PAPER NUMBER
1645	8

DATE MAILED: 06/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/770,916	Frank et al
Examiner	**Group Art Unit**
Duffy	1645

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1-20 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claim(s) 1-20 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Interview Summary, PTO-413

☐ Notice of Informal Patent Application, PTO-152

☐ Other _____

Office Action Summary

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, 5 and 17, drawn to methods of inhibiting infection using the polypeptide antigen vaccine, classified in class 424, subclass 184.1.

II. Claims 3, 4, 11, 12, 13 and 14, drawn to methods of inhibiting infection using the nucleic acid vaccine, classified in class 514, subclass 44.

III. Claims 15 and 16, drawn to methods of inhibiting infection using an antibody that binds the polypeptide antigen, classified in class 424, subclass 130.1.

IV. Claims 6 and 7, drawn to methods of diagnosing infection using hybridization probes, classified in class 435, subclass 6.

V. Claim 8 and 9, drawn to methods of diagnosing infection using primer amplification, classified in class 435, subclass 91.2.

VI. Claim 10, drawn to methods of diagnosing infection using polypeptide antigen to detect antibody in a sample, classified in class 435, subclass 7.1.

VII. Claims 18-20, drawn to antibodies, classified in class 530, subclass 388.1.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I, II and III are mutually exclusive and independent methods of treatment of disease. The method of Inventions I or III do not require the genetic construct of Group II. The method of Invention II, neither requires or uses the protein sequence used in Invention I nor the antibody of the Invention III. As such, each of the Inventions rely upon mutually exclusive and independent reagents in the methods of the Inventions *per se*. Each of the reagents to perform the independent and distinct methods are not required to preform the other methods and as such would require independent and

distinct searches. The methods are therefore deemed independent and distinct because utilize different reagents (proteins, nucleic acids, and antibodies) that have different structures.

Inventions VII and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody can be used to purify the antigen or in a diagnostic test to detect the presence of infection or the microorganism in a environmental sample.

Inventions II, IV, V and VI are mutually exclusive and independent methods of use using nucleic acids or polypeptides. Each of the methods are distinct each from the other because distinct methods which differ in the method objectives, method steps (i.e. treatment/protection from infection, diagnosis or detection) steps and in the reagents used (vaccine vectors having nucleic acids encoding a protein, probes, primer pairs and polypeptides). For example, the methods that use the nucleic acids are distinct from the methods that use the polypeptides because the polypeptide is not required to make the nucleic acid nor is required to practice the methods using the nucleic acids. Methods which determine the presence of the nucleic acid will not determine the presence of the polypeptide, for example hybridization methods with complementary nucleic acids are used to determine the presence of the nucleic acid sequence, however the polypeptide is assayed based on protein activity or by immunological means. These methods are distinct each

from the other because they administer reagents which are chemically distinct. The methods that employ the same reagent are distinct each from the other because they have different goals and different method steps. As such, search and examination for one method does not encompass the other methods.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, as shown by their different classification, and in the absence of restriction would place an undue search and examination burden on the examiner, restriction for examination purposes as indicated is proper.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

6. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy, Ph.D. whose telephone number is (703) 305-7555. The examiner can normally be reached on Tuesday-Saturday from 10:00 AM to

6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.

Patricia A. Duffy, Ph.D.
June 8, 2002

Patricia A. Duffy, Ph.D.
Primary Examiner
Group 1600